

## **Business Plan for a “CEN Workshop Agreement for Biosafety Professional (BSP) Competence”**

### **1. Background**

This project is the outcome of a series of workshops convened by the European Biosafety Association (EBSA) Biosafety Professional (BSP) Competence Task Group. The first meeting was held in February 2006.

The Task Group is composed of representatives from different European countries<sup>1</sup> with the purpose of writing a draft document that defines the competency of a BSP. The document should be written and structured in such a way that it could provide means to facilitate any future initiatives of institutions for education of biosafety professionals, be it as newly developed programmes or as courses integrated into existing certified training curriculums.

The Task Group members have brought to the table initiatives that have started at the local level in several European countries (UK, Belgium, Switzerland, The Netherlands, ...). This is a subject of great interest to many such as the World Health Organisation (WHO), the European Commission, national competent authorities and biosafety groups since the BSP is seen as instrumental in the design and management of laboratory biosafety and biosecurity programmes to ensure protection of workers, public health and the environment arising from activities involving potentially hazardous biological materials and preventing their misuse.

For adequate laboratory biosafety and laboratory biosecurity the main pillars are a biorisk management system and the appointment of a BSP with the appropriate skills to develop and manage such a programme. Through a CEN Workshop agreement process initiated by the American Biological Safety Association (ABSA), EBSA and Det Norske Veritas (DNV), and financed primarily by the European Commission, CWA 15793:2008 on laboratory biorisk management was approved by its participants and published in February 2008.

CWA 15793 recognizes a key role for the biosafety professional in a laboratory biosafety and biosecurity management programme. While CWA 15793 defines the role of the BSP in general terms, the present initiative complements the CWA by clearly defining the role profile, the tasks and competency requirements for the BSP, as well as corresponding training curriculum for BSP, setting a framework for establishing training programmes.

*A tour de table* at the first meeting of the EBSA BSP Competence Task Group made it clear that, although all the countries that belong to the European Union and European Free Trade Agreement share a common regulatory system, their interpretations of the European Community regulations differ:

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<sup>1</sup> Austria, Belgium, Germany, The Netherlands, Sweden, Switzerland, UK

- The European Commission Directives and Regulations do not identify the function of the BSP but make only a statement regarding the “responsibility of the employer” to take measures necessary for the safety and health protection of workers, including prevention of occupational risks and provision of information and training
- Some countries recognize the function of the BSP, but most commonly this is restricted to work involving genetically modified organisms only
- Some have defined tasks for the BSP
- Some countries have a short initial training requirement, without an exam
- Some countries accept only persons with certain degrees
- Few countries have a procedure to assess BSP competency

Since a BSP has a key role contributing to biorisk management programmes, it is important to clearly define the competence based on skills, knowledge and experience required to fulfill the function. EBSA proposes to fill this gap through a CEN Workshop Agreement process.

## **2. CEN Workshop proposer**

European Biosafety Association – EBSA ivzw  
c/o DECHEMA e.V.  
Theodor-Heuss-Allee 25  
60486 Frankfurt am Main  
Germany

## **3. CEN Workshop Objectives**

Within an organization the responsibilities for a biorisk management programme are held by senior management. But the competence of the BSP is key to develop, implement, maintain and continually improve a biorisk programme based on a management system.

The objective of the CEN Workshop is to develop and promote consensus on the adoption of:

1. the tasks of a BSP;
2. the skills of a BSP;
3. the model role profile of a BSP;
4. a curriculum to set and achieve the required skills, divided into:
  - a basic curriculum required for all biosafety professionals,
  - supplemented as needed by specialist areas.

The CEN Workshop must be in agreement with CWA 15793.

There do not appear to be management system aspects to be dealt with in the CEN Workshop that make it necessary to prepare a justification in accordance with ISO Guide 72:2001. In addition, conformity assessment aspects are not foreseen to be dealt with. However, should this change, the ISO CASCO toolbox documents (ISO CASCO 17007) will be respected and the general requirements of EN ISO/IEC 17024 “Conformity assessment – General requirements for bodies operating certification of persons” will be respected in the work of the CEN Workshop.

#### **4. Workshop Work Programme**

The Business Plan was posted on the CEN Workshop website ([www.cen.eu](http://www.cen.eu)) for public comment 60 days prior to the Kick-Off Meeting.

The Kick-Off Meeting of the CEN Workshop was held at the DECHEMA premises in Frankfurt on 17 December 2009, and was open to any interested party. The Kick-Off meeting approved the Business Plan, including any amendments agreed in response to the public comments made on the draft.

Following approval of the CEN Workshop Business Plan at the Kick-Off Meeting, interested parties could register at the CEN Workshop Secretariat and received the initial working document for review. The first plenary meeting of the CEN Workshop, open to registered parties only, was held on 18 December 2009 at the DECHEMA premises in Frankfurt immediately following the Kick-Off meeting. A second plenary meeting open to registered parties was held on 27-28 May 2010 at the DECHEMA premises in Frankfurt.

A draft of the CWA will be made available on the CEN website for public comments for a period of at least 60 days. Registration for participation in the CEN Workshop will remain open to interested parties until the end of the public consultation phase.

Timetable:

- Kick-off Meeting, 17 December 2009 at DECHEMA premises in Frankfurt
- A working document was distributed to participants for comments upon registration as a participant of the CEN Workshop
- First CEN Workshop Plenary Meeting, 18 December 2009 at DECHEMA premises in Frankfurt
- Written comments from CEN Workshop participants by 15 February 2010 to the NEN secretariat
- Revised draft working document distributed to participants in preparation for second plenary meeting before 3 May 2010

- Second CEN Workshop Plenary Meeting, 27-28 May 2010 at DECHEMA premises in Frankfurt
- 11 June 2010: NEN distributes modified draft to WS 53
- 9 July 2010: deadline WS 53 for sending in comments
- 15 September 2010: NEN distributes modified draft to WS 53
- 15 October 2010: deadline WS 53 for sending in comments
- 15 November 2010 – 15 January 2011: public enquiry (PE, draft available on CEN website)
- writers modify PE draft based on received comments
- 11 April 2011: draft to WS 53 for discussion 3rd meeting
- 10 and 11 May 2011: 3rd plenary meeting in Brussels

The language of the CEN Workshop and its documentation will be English. The final text will be published in English.

## **5. CEN Workshop Organisation**

EBSA BSP Competence Task Group has provided a working document to initiate the discussions (doc. CEN/WS 53 N 03).

During the Kick-Off meeting, the appointment of the following two Co-Chairs was approved:

Co-Chair: Helmut Bachmayer

Co-Chair: Ursula Jenal

The responsibilities of the CEN Workshop Co-Chairs are the following:

- To preside at the CEN Workshop plenary meetings
- To manage the consensus building process

During the Kick-Off meeting, the appointment of NEN, the Dutch CEN member, was approved to perform project management tasks and to hold the Workshop Secretariat of the CEN Workshop.

The following activities will be carried out:

- registration of CEN Workshop participants
- electronic document distribution
- organising CEN Workshop plenary meetings
- producing CEN Workshop meeting reports and action lists
- administrative contact point for WS
- managing CEN Workshop membership lists

- managing CEN Workshop document registers
- follow-up of action lists
- consolidation of the comments received on the draft during the enquiries and distribution to the participants for discussion and resolution
- advice on consensus building mechanisms
- distribution of comments, resolutions and reports to participants
- checking conformity of draft to CEN rules
- advisory role on structure of document
- organise and administer the contractual framework as needed
- manage the project budget

The proposers have provided a Project Coordinator, whose responsibilities will include the following:

- To ensure liaison with relevant CEN/TCs (e.g. CEN/TC 140 - In vitro diagnostic medical devices and ISO/TC 212 - Clinical laboratory testing and in vitro diagnostic test systems and other relevant organizations, for example the World Health Organization)
- To keep BT/WG 192 - Qualification of professions/personnel informed about the work of the CEN Workshop.
- To represent the CEN Workshop in outside meetings in cooperation with the CEN Management Centre (CMC)
- To interface with the CMC regarding strategic directions, problems arising, external relationships, etc.
- To ensure that the CEN Workshop delivers in line with the Business Plan
- To act as a contact point to respond to any queries of interested parties
- To administer CEN Workshop web-pages open to non-members, assisted by DECHEMA as EBSA's administration office
- To draft agendas to manage venue and related aspects, assisted by DECHEMA as EBSA's administration office
- To actively disseminate information to stakeholders and CWA potential participants, assisted by DECHEMA as EBSA's administration office

## 6. Resources

The main funding will be provided by the European Commission (Directorate-General Justice, Freedom and Security) through CEN, with additional funds through

### a) sponsors

Global Partnership Program  
Department of Foreign Affairs and International Trade Canada  
125 Sussex Drive  
Ottawa, Canada

Schweizerische Erdgenossenschaft  
Eidgenössisches Departement für Umwelt, Verkehr, Energie und Kommunikation UVEK  
Bundesamt für Umwelt BAFU  
Eidgenössisches Departement des Innern EDI

Bundesamt für Gesundheit BAG  
Bern  
Schweiz

Ministerie van Volkshuisvesting Ruimtelijke Ordening en  
Milieubeheer (VROM)  
Rijnstraat 8  
P.O. Box 20951  
2500 EZ the Hague  
The Netherlands

International Science and Technology Center (ISTC)  
Krasnoproletarskaya ulitsa 32-24  
127473 Moskau  
Russia

The European Society for Clinical Microbiology and Infectious  
Disease (ESCMID) will, in specific cases, sponsor participants to  
the workshop.

- b) Registered organisations including academia, industry, Government  
Departments, etc. will be required to pay a one-time fee of Euro 200 as a  
contribution to the costs of the Workshop, which will allow for the  
participation of one representative in the Workshop consensus process. The  
number of individuals from registered organisations admitted to the  
Workshop mailing list will not be limited. However, participation in meetings  
may be limited for logistical reasons.

## 7. Contact points

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